K073527 #1/2

510(k) Summary of Safety and Effectiveness
VariAx™ Elbow System

Proprietary Name:	VariAx™ Elbow System
Common Name:	Bone plates and screws
Classification Name/Reference:	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Device Product Code:	87 KTT
Proposed Regulatory Class:	Class II
For Information contact:	Francisco Haro, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5493 Fax: (201) 831-6038
Date Summary Prepared:	December 14, 2007

FEB 14

Description:

This submission is a line extension to the Stryker® Plating System. The components of the VariAx™ Elbow System are intended to add different types of plates and screws to the Stryker® Plating System portfolio.

Indications:

The VariAx™ Elbow System is intended for fracture fixation of long bones. Indications include:

- Distal Humerus
- Proximal Ulna

Substantial Equivalence:

The VariAx™ Elbow System is substantially equivalent to the Stryker® Foot, Profyle®, Stryker® Locked Plating, and Universal Distal Radius Systems in regards to intended use, design, materials, and operational principles as a fracture plating system.

K073527 #2

Executive Summary:

Device Description:

This submission is a line extension to the Stryker® Plating System. The components of the VariAx™ Elbow System will be based on the component designs of the Stryker® Foot, Profyle®, Stryker® Locked Plating, and Universal Distal Radius Systems which were determined substantially equivalent in the following 510(k)s K063875, K062498, K050512, and K040022. Refer to Table 1 in Section 11 for a description of each predicate component, subject component, and modifications.

Indications:

The VariAx™ Elbow System is intended for fracture fixation of long bones. Indications include:

- Distal Humerus
- Proximal Ulna

Substantial Equivalence:

The VariAx™ Elbow System is substantially equivalent to the Stryker® Foot, Profyle®, Stryker® Locked Plating, and Universal Distal Radius Systems in regards to intended use, design, materials, and operational principles as a fracture plating system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2008

Howmedica Osteonics Corp.
% Mr. Francisco Haro
325 Corporate Drive
Mahwah, NJ 07430

Re: K073527
Trade/Device Name: VariAx™ Elbow System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: December 14, 2007
Received: December 17, 2007

Dear Mr. Haro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073527

Device Name: VariAx™ Elbow System

Indications for Use:

The VariAx™ Elbow System is intended for fracture fixation of long bones. Indications include:

- Distal Humerus
- Proximal Ulna

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073527